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PATENT
Customer No. 22,852
Attorney Docket No. 08888.0557

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
R. DARTEIL et al.) Group Art Unit: 1,646
Application No.: 10/018,729) Examiner: R. KELLY
International Filing Date: June 22, 2000)
U.S. National Stage Filing Date: December 18, 2001)
For: SYSTEM FOR REGULATION OF EXPRESSION USING PPAR NUCLEAR RECEPTORS)))
Commissioner for Patents P.O. Box. 1450	

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Alexandria, VA 22313-1450

In a Restriction Requirement dated August 26, 2003, the Examiner required restriction of the claims of this application into twenty Groups, and required Applicants to elect a single Group for examination in this application. In response, Applicants elect Group IV, claims 1-23, 25-27, 29, and 31, drawn to a nucleic acid encoding modified PPARy, with traverse.

All of the claims of this application share a special technical feature, which is an improved system of inducible expression of genes using perosixome proliferator-activated receptors (PPAR) as transcriptional regulators. The special technical feature shared by the claims defines the invention over the prior art by providing numerous advantages over the systems of the prior art, such as substantial induction, tolerance (in particular for *in vivo* use), strength, and conditions of use. See the present specification at pages 5-6. For at least this

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

U.S. Patent Application No. 10/018,729

Attorney Docket No.: 08888..0557

reason, restriction of the claims into the various Groups is improper, and the Restriction Requirement should be withdrawn.

Furthermore, Applicants respectfully submit that the Office has improperly limited the scope of the claims through the Restriction Requirement. For example, in issuing the Restriction Requirement, the Office has, without Applicants' permission or approval, limited the scope of claim 1 to specific species recited in the specification and certain dependent claims. Applicants respectfully submit that they have a statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose. Issuing a Restriction Requirement by incorporating an unclaimed limitation into a claim in an effort to limit that claim to disclosed species or embodiments, with the idea that Applicants would have to carve up that claim and pursue the non-elected subject matter in a separate application, violates this right under § 112. Indeed, the C.C.P.A. has characterized such action as tantamount to a refusal to examine. See In re Weber, 198 U.S.P.Q. 328 (C.C.P.A. 1978); In re Haas, 198 U.S.P.Q. 334 (C.C.P.A. 1978). For at least this reason, the Restriction Requirement is improper, and should be withdrawn.

In addition, the Restriction Requirement makes it impossible for Applicants to obtain the full scope of their invention, even if every Group were to be pursued in all twenty applications that would be required as a result of the Restriction Requirement. That is, even if Applicants pursued each and every Group set forth in the Restriction Requirement, they still would not obtain full coverage for claim 1, which generically recites a composition comprising, among other things, a nucleic acid encoding "a PPAR". In other words, the scope of protection provided by all twenty required applications directed to the species of generic claim 1 identified by the Office would not equal the scope recited in claim 1, as filed. Thus, the Restriction

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U.S. Patent Application No. 10/018,729 Attorney Docket No.: 08888.0557

Requirement is improper and should be withdrawn because it completely eliminates subject matter from the application.

Furthermore, the Restriction Requirement does not include claim 30 in any Group. Thus, it eliminates subject matter from the application without permission from Applicants. For at least this reason, the Restriction Requirement is improper, and should be withdrawn.

Applicants additionally submit that a thorough search and examination of the claims of Group IV would necessarily encompass a search and examination of the claims of Groups VIII and XII. Thus, a search and examination of the non-elected claims of these Groups with the claims of Group IV would not place a serious additional burden on the Examiner. MPEP § 803 states that "if the search and examination of the entire application can be made without serious burden, the examiner <u>must</u> examine it on the merits" (emphasis added herein by Applicants). It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office.

In the event that the Office does not withdraw the Restriction Requirement, Applicants respectfully submit that the non-elected claims of Groups XVI and XVIII should be re-joined with the product claims of Group IV, once one or more product claims are found to be allowable. In response to *In re Ochiai* and *In re Brouwer*, the Commissioner set forth guidelines for treatment of non-elected process claims. See the Official Gazette, 1184 OG 88 (March 26, 1996). These guidelines have been incorporated into MPEP § 821.04. Under these PTO guidelines, "rejoinder practice" applies to Applicants who have elected claims to a product over claims to a process in compliance with a Restriction Requirement. When it is established that a product claim is allowable, withdrawn process claims that depend from, or otherwise include all the limitations of, the allowable product claim <u>must</u> be rejoined. Applicants respectfully submit that this procedure applies to the present claims of Groups XVI and XVIII.

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U.S. Patent Application No. 10/018,729 Attorney Docket No.: 08888.0557

In view of the above remarks, Applicants request reconsideration and withdrawal of the Restriction Requirement. Furthermore, Applicants request re-joinder of Groups VIII, XII, XVI, and XVIII with elected Group VI. In the event that the Office does not withdraw the Restriction Requirement, Applicants reserve the right to Petition the Commissioner to review the Restriction Requirement, and/or to prosecute the non-elected claims in divisional or continuation applications.

Applicants believe that no Petition or fee is due in connection with the filing of this Response. However, if any Petition or fee is due, please grant the Petition and charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Date: September 26, 2003

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